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March 24, 2005

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1051 Rockville, Maryland 20852

In re: Korangy Radiology Associates, P.A., et al.

FDA Docket No. 2003H-0432

Dear Sir/Madam:

Enclosed for filing in the above-referenced matter please find an original and one copy of the Respondents' Request for Protective Order.

A draft order is also enclosed.

Thank you for your attention to this filing. Please contact me with any questions.

Sincerely,

Henry E Schwartz

Enclosures

cc:

Amile Korangy, M.D. Jennifer E. Dayok, Esquire Marci Norton, Esquire Hon. Daniel J. Davidson, ALJ

UNITED STATES OF AMERICA BEFORE THE FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:

* ADMINISTRATIVE COMPLAINT
KORANGY RADIOLOGY ASSOCIATES, * FOR CIVIL MONEY PENALTY
P.A., t/a BALTIMORE IMAGING
CENTERS, * FDA Docket: 2003H-0432
And * AMILE A. KORANGY, M.D. *

RESPONDENTS' REQUEST FOR PROTECTIVE ORDER

Respondents, by their undersigned attorneys, hereby request that the information pertaining to this case, made publicly available by the FDA, through their website and otherwise, be limited to protect privileged information under (21 CFR 17.23(d)(3) and 21 CFR 17.28(b)), and to avoid an unwarranted invasion of personal privacy (21 CFR 17.28(b)). This request is made pursuant to 21 CFR 17.28(b)(6).

Specifically, Respondents wish to protect information relating to their tax returns and financial status and property ownership, as well as property ownership that the FDA has sought to "impute" to Respondents, though such property may not be held in the name of Respondents.

In particular, protection is sought of the following documents or portions thereof:

- 1. Complainant's Post-Hearing Brief on Penalty Amount;
- 2. Pre-Filed Direct Testimony of Amile A. Korangy, M.D. (Answers 22-24, 27, 28 and 31; Exhibits 2-7);
 - 3. Initial Decision of December 17, 2004 (pages 6-8);
 - 4. Respondents' Proposed Findings of Fact (Sections 18-23); and
- 5. Complainant's Brief in Opposition to Respondents' Appeal and Request for Oral Argument (pages 19-22).

For the foregoing reasons, Respondents respectfully request that a Protective Order be issued, limiting the publicly available record in the instant case.

Respectfully submitted,

Henry E. Schwarz

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this $\underline{\mathcal{W}}$ day of March, 2005, a copy of the foregoing Respondents' Request for Protective Order was mailed, postage prepaid, to Marci Norton, Esquire, and Jennifer Dayok, Esquire, Office of the General Counsel, Food and Drug Administration, 5600 Fishers Lane, GCF-1, Rockville, Maryland 20857.

Henry E. Schwartz

UNITED STATES OF AMERICA BEFORE THE FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:

KORANGY RADIOLOGY ASSOCIATES, *

P.A., t/a BALTIMORE IMAGING

CENTERS,

FDA Docket: 2003H-0432

ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY

And

AMILE A. KORANGY, M.D.

* * * * * * * * * * *

PROPOSED ORDER

Respondents filed a request for Protective Order, seeking, pursuant to 21 CFR 17.28, that the information pertaining to the instant case, made publicly available by FDA, through its website and otherwise, be limited to protect privileged personal and commercial information. Specifically, Respondents have requested that information relating to their tax returns and financial status and property ownership, as well as property ownership of others that may be imputed to Respondents by FDA, be redacted.

Accordingly, it is ORDERED, ADJUDGED, AND DECREED, that:

Respondents' request for Protective Order is hereby GRANTED, and it is Ordered that future availability of documents to the public be limited in accordance with this Order, and that the information available on the FDA website be modified in conformance with this Order.

The following documents or portions thereof are covered by the terms of this Order:

- 1. Complainant's Post-Hearing Brief on Penalty Amount;
- 2. Pre-Filed Direct Testimony of Amile A. Korangy, M.D. (Answers 22-24, 27, 28 and 31; Exhibits 2-7);
 - 3. Initial Decision of December 17, 2004 (pages 6-8);
 - 4. Respondents' Proposed Findings of Fact (Sections 18-23); and

5. Complainant's Brief in Opposition to Respondents' Appeal and Request for Oral Argument (pages 19-22).

Daniel J. Davidson Administrative Law Judge U.S. Food and Drug Administration Room 9-57, HF-3 5600 Fishers Lane Rockville, Maryland 20857

Proposed by:

Henry E. Schwartz

Attorney for Respondents

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this day of March, 2005, a copy of the foregoing Proposed Order was mailed, first class, postage prepaid, to Complainant's Counsel, as follows:

Marci Norton, Esquire
Jennifer Dayok, Esquire
The Center for Devices and Radiological Health
United State Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, Maryland 20857
Telephone: 301.827.1141